

Linnerson had been interviewed previously by SA Scavdis.

Linnerson was the Managing Partner of his clinic until 2016. After that time, he stayed on as the Chief Operating Officer (COO). There are three offices of SCWC.

Fingertick blood testing was part of the appeal of Therasos technology when they approached Linnerson's practice group, Southwest Contemporary Women's Care ("SCWC").

SCWC had a Product Committee which would review marketing proposals for new drugs and devices to be used by the clinic. Each office in the group had a representative on the committee. When the practitioners were approached by vendors, they would be referred to the Product Committee, which would review the product and make a recommendation to the partners whether the new products should be used in the practice. The practitioners were "very intelligent." Linnerson sat in on the Product Committee in his capacity as COO. The Product Committee asked vendors to present data because "we [the practitioners] are scientists, we need to see data." "A lot" of the presentations are new medications. New products are "always protected and expensive." Linnerson's preference is to wait until a product has been on the market for some time before using it in practice.

"Labs [didn't] approach" the product committee "ever." When Therasos did approach, the fingertick technology they described was attractive because "needle-phobia" was an issue for patients. Therasos did present data and claimed they had "met all regulations." Linnerson knew Therasos was "in Walgreens, so some agency must have approved them." Linnerson assumed Therasos was approved by regulators. The data Therasos presented "indicated results were on par to large American labs." The SCWC practitioners were "not pathologists,"

On June 13, 2019, Assistant U.S. Attorney Robert Leach, Assistant U.S. Attorney John Bostic, and I interviewed Steve Linnerson, MD, regarding his experience with Therasos blood testing. Food and Drug Administration Office of Inspector General Special Agent George Scavdis was present during part of the interview. The following Memorandum of Interview is based on both my field notes and my independent recollection of the interview. During the interview, Linnerson provided the following information:

CASE NUMBER	:	[REDACTED]
PERSON INTERVIEWED	:	Steve Linnerson MD
PLACE OF INTERVIEW	:	[REDACTED]
DATE OF INTERVIEW	:	06/14/19
TIME OF INTERVIEW	:	12:15-1:20 PM MST
INTERVIEWED BY	:	AUSA Robert Leach AUSA John Bostic Postal Inspector Matthew Norleet

MEMORANDUM OF INTERVIEW

UNITED STATES POSTAL INSPECTION SERVICE



they were "not trained on the data for" a lab like Theranos. They are trained on evaluating drugs. After the presentation, the Product Committee brought Theranos to the partners and recommended that SCWC use Theranos, which it did.

The testing menu was a "big draw" in the medical community. Linnerson was impressed at the costs Theranos offered for tests; cholesterol, for example, was half the cost of the other labs.

The Theranos presentation did not talk about using vein draws. Linnerson only learned that Theranos did vein draws from patients after SCWC began referring them. Theranos representatives told Linnerson "everything is fingerstick. Here is our list."

Linnerson believed Patients chose to use Theranos because of money, and the convenience of the location in the SCWC building.

Linnerson recalled his grandfather told him "if it sounds too good to be true. . . " and in retrospect he believed that Theranos claims were too good to be true. Linnerson said, on the other hand, was "pretty amazed by [his] smartphone, so [he] guessed that's medicine in the future."

As COO of SCWC, Linnerson was also the property manager of the building in which the clinic was located. Theranos rented space in the building downstairs, and told SCWC that their office would be the first medical office with a Theranos test site on premises. However, SCWC did not have a contract with Theranos.

As property manager, Linnerson was aware of the preparations Theranos made to the space, but Theranos said it required a "special room" for its "equipment" which it said was "very proprietary." Linnerson had a master key to open any door in the building during emergencies, except that room within the Theranos office. Linnerson wanted assurance that nothing in the room could create an emergency, and he was told the room contained "just proprietary equipment that runs the tests." Linnerson believed Theranos samples went to Skysong, he thought medical labs occupied entire buildings, and he knew how big the proprietary room in the Theranos office was, so he believed Theranos ran its lab tests at Skysong.

Linnerson knew from his own experience that medical devices had to be FDA approved. When asked if Theranos representatives told him Theranos testing equipment was FDA approved, he recalled that Theranos said it "compared to all national[ly-known] labs."

Linnerson said there is a very powerful explanation for the importance of HCG tests that is something you would teach residents studying obstetrics. The words "'you are pregnant' are very thrilling or very frightening" to hear from a doctor.

A 16-cell embryo is called a Morula. From days 14-28, pregnancy occurs in the tube. Around day 28, it migrates and implants; once the embryo implants, the body produces HCG. From weeks four to seven, HCG doubles every 48 hours. Although the absolute value varies between patients, viable pregnancies always show continually-increasing HCG levels. A pregnancy urine test determines whether HCG is present, resulting in a negative test if the HCG level is less than 20, and a positive test if the HCG level is over 20. More precise HCG tests are used to observe (1) losing babies (miscarriages) or (2) outside the uterus (ectopic) pregnancies. Ectopic pregnancies can be tubal or abdominal. Tubal pregnancies can result because gonorrhea and chlamydia cause scarring to the tube, which can cause the pregnancy to get stuck. A stuck pregnancy can cause bleeding, losing the tube, or death. Methotrexate (also called MTX) is a chemotherapy drug prescribed to dissolve ectopic pregnancies.

More than one lost pregnancy is a risk factor for future miscarriage. A patient with recurrent miscarriage would know that a decline in HCG means a lost pregnancy, and would expect to go home and bleed.

Medical practitioners would not make a diagnosis off one HCG test alone. HCG tests are used to monitor a pregnancy until it can be seen on an ultrasound. A dropped HCG value would indicate a bad lab test, not a true HCG value. When a patient is prescribed MTX, the physician would follow the labs until the HCG level is below 20. HCG tests are used to follow treatment of chronic miscarriage.

Linnerson became aware of problematic HCG test results from Theranos through [REDACTED] case. G [REDACTED] received a Theranos test that showed a drop in HCG levels after several miscarriages. G [REDACTED] was aware of the significance of HCG testing and was distressed by the result. The result was erroneous, and G [REDACTED] later gave birth to a baby from that pregnancy. She did not return to the same clinic when she later became pregnant again. DNP Audra, G [REDACTED] probably primary physician, told Linnerson "she hates me" but Linnerson explained that G [REDACTED] probably just did not want to return to the same place where she had such an upsetting memory.

Similar results came up at a provider meeting with two other questionable HCG tests. SCWC decided to do a side by side study with other labs to decide whether to continue referring patients to Theranos. The practice had never done anything like that before, but Theranos was so cheap and convenient they wanted to give it a chance. The SCWC Product Committee included Audra and handled all the discussions with Theranos about the study. Linnerson trusted the Product Committee. However, the problems they experienced with Theranos testing were "wild throws outside what [they] were used to seeing, outside [their] collective experience as a group of 20 clinicians."

At the time, Linnerson had 31 years of experience as an OB-GYN. He had been using HCG tests for about 10 years before Theranos, had attended approximately 3,000 deliveries, and ordered probably 5,000 HCG tests, maybe "some less" because of patients whose pregnancies were detectable by ultrasound before they saw him.

The study data would "have to be statistically significant," but Theranos "stood out more than the other two." The study was "really a small sample size" and Linnerson did not recognize the name ARUP. At the time, Linnerson "wondered about the workflow" of Theranos taking fingerstick samples and the other labs using vein draws as part of the study. After Theranos completed the study, Linnerson's opinion was that the data did not show Theranos performed well enough to recommend using its services. Linnerson "could not see how it got past the FDA." Linnerson had "years of experience" with Sonora Quest Labs without any problems, but had three problems with Theranos in a short period of time, and he saw problems with the study Theranos conducted to try to prove its reliability. Linnerson had always taught new doctors not to "jump on new technology" but to wait three to five years. When reviewing the results of the Theranos side by side study, with "senior people in the room," SCWC said "we're not going to do this to patients."

After deciding to stop referring patients to Theranos for HCG tests, SCWC had to decide whether to use Theranos for other lab tests. Linnerson does not recall speaking to Theranos representatives about SCWC's decision not to use their testing, although he was in contact with them as the property manager. Linnerson thought Audra may have spoken with Theranos about SCWC's decision.

After he was contacted by federal investigators, Linnerson reviewed SCWC records with its information technology staff and found 330 HCG tests ordered from Theranos between 2014 and 2016, along with hemoglobin and some other tests, for "maybe 100 patients."

Linnerson did not recall seeing any news stories about Theranos. He did recall seeing advertising for Theranos, but he did not recall if he saw it before SCWC began referring patients. After Theranos moved into the building, Linnerson walked downstairs one evening after 5:30 and asked himself "who's getting married" in the lobby, because Theranos was hosting a weekly party with bar tables, cocktails, champagne, and people in black suits. Suits are unusual in Arizona.

In September or October 2016, Theranos stopped operating and bought their way out of the lease. When Linnerson went back into the "special" room where Theranos had changed the lock, "nothing [had] changed."

Matthew Norfleet
Matthew Norfleet
United States Postal Inspector

09/12/19